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09/214-984

APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/214,984	03/08/99	SIROTNAK	F MSK. P-003-US

021121 HM12/0720  
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EXAMINER

DATE MAILED: 07/20/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 O.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(e).

#### Disposition of Claims

- ☒ Claim(s) 1--12 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1--12 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-848.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-848
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1611

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites 'composition'. This term is open ended and begs the question ' what other components are intended ?'. The specific nature of the components and the number of components is not specified. The claim fails to distinctly claim the invention.

Claim 9 cites ' at least one additional cytotoxic or antitumor compound".

This fails to specify the specific compound. The claim is indefinite.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1611

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGraw et al., USP 5,354,751. The prior art specifically articulates on column 38, Example 7 10-propargyl 10-deazaaminopterin. The prior art further teaches on column 24, lines 58-60 the evaluation of the said compound in suppression of tumor growth. Also see the abstract. The instant invention differs from the prior art in teaching 10-propargyl-10 deazaaminopterin substantially free from deazaaminopterin. However, one skilled in the art would recognize the compounds as antifolates. It is well known in the art that antifolates are used in the treatment of tumors. See column 2 of the prior art. Furthermore, the ordinary artisan would have been motivated to prepare pure isolates of the compounds as impurities present could be potentially toxic. It is customary to use pure compounds particularly when it is contemplated to use them in tumor therapy. Therefore, the instant claims are rendered obvious over the cited prior art. As the applicants are aware combination of drugs are used in cancer chemotherapy as composition of cyclophosphamide, vincristin, cytosinearabioside etc.,.

Art Unit: 1611

Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starling et al., Cancer Chemotherapy Reports Vol 58, Sep/Oct 1974..

The prior art teaches the combination of chemotherapeutic agents for treating cancer. The teachings of this reference in combination of the above cited reference would render the instant method claims obvious. The DeGraw' patent teaches the use of pterine derivatives to treat tumors. It does not teach the use of combination of drugs. This deficiency is cured by the Starling reference. It would have been obvious to one skilled in the art to use pterins in combination of other chemodrugs as Fluorouracil etc. as taught in Starling and achieve the instant method of treatment.

Any inquiry concerning this communication should be directed to PK Sripada at telephone number (703) 308-4717.

PK

07/15/99

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